K103815

5. 510(k) Summary

This summary of safety and effectiveness is provided as part of the Premarket Notification in compliance with 21CFR. Part 807, Subpart E, Section 807.92

JAN 25 2011

1) Submitter's name, address, telephone number, contact person

Philips Ultrasound, Inc.
P.O. Box 3003
Bothell, WA 98021-3003
Nancy Burke, Regulatory Affairs Specialist
Telephone: (425) 487-7371
Facsimile: (425) 487-8666
E-mail: Nancy.Burke@philips.com

Date prepared: December 15, 2010

2) Name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known:

Common/Usual Name:	Picture Archiving and Communications Systems Workstation
Proprietary Name:	Q-Station
Classification Name:	CFR 892.2050, system, image processing, radiological, Product code LLZ, Class II

3) Substantially Equivalent Devices

Philips Ultrasound believes that the Q-Station 1.0 software is substantially equivalent to other commercially available products, specifically Xcelera (K061995).

3) Device Description

Q-Station is workstation software designed for managing, viewing and reporting qualitative and quantitative image data from ultrasound exams. It includes advanced analysis via QLAB integration (QLAB 8.0) and provides integrated tools that allow users to manually assess and score cardiac wall motion and export images and/or exams and reports. It supports connectivity to ultrasound systems, PACS, other DICOM storage repositories, and Philips StressVue ECG systems to aid clinicians in diagnostic activity. Q-Station supports QLAB Plug-ins.

4) Intended Use

Q-Station software is a software application package. It is designed to manage; view and report image data acquired by ultrasound systems and cardiac waveform data from Philips StressVue ECG systems.

5) Technological comparison to predicate devices

Both Philips Q-Station and Philips Xcelera are software applications for medical image and data review and patient report preparation. Both are DICOM compatible and allow for the storage and save/retrieve of image data and reports. Both are workstation software applications intended to be used with medical DICOM images and waveforms acquired from other modalities.

6) Non-clinical performance data

No performance standards for PACS systems or components have been issued under the authority of Section 514. The Q-Station software has been designed to comply with the following voluntary standards:

- NEMA PS 3.1 - 3.18 (2008), Digital Imaging and Communications in Medicine (DICOM) Set
- IEC/ISO 10918-1:1994 Technical Corrigendum 1:2005, Information technology – Digital compression and coding of continuous-tone still images

Software development for the Q-Station software follows documented processes for software design, verification and validation testing. A risk assessment has been completed to identify potential design hazards that could cause an error or injury based on the use of the quantification results. Appropriate steps have been taken to control all identified risks for this type of image display and quantification product.

7) General Safety and Effectiveness Concerns

The device labeling contains operating instructions for the safe and effective use of the Q-Station software.

8) Conclusions

The Q-Station software is designed and manufactured to meet United States and international standards for the display and quantification of images acquired on Ultrasound devices. The system is designed to incorporate components common to all image viewing systems for the display, manipulation and quantification tasks within a clinical setting. The Q-Station software incorporates features of predicate devices cleared through premarket notification and no new issues of safety or effectiveness are raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Philips Medical Systems
Mr. Mark Job
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

JAN 25 2011

Re: K103815
Trade/Device Name: Q-Station Software 1.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: December 28, 2010
Received: December 29, 2010

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary Pastel, ScD.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Attachment A

1. Indications for Use Statement

510(k) Number (if known): K103815

Device Name: Q-Station software 1.0

Indication for Use:

Q-Station software is a software application package. It is designed to manage, view and report image data acquired by Ultrasound systems and cardiac waveform data from Philips StressVue ECG systems. Q-Station offers support for QLAB plug-ins for analysis, quantification and reporting of data from ultrasound systems.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-the-counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K103815